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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,218

04/15/2004

Paolo C. Trubiano

3085.ENC

1170

7590

01/09/2007

Karen G. Kaiser  
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EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/826,218	TRUBIANO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

#### DETAILED ACTION

Claims 1–21 are pending. Claims 1–17 are considered on the merits. Claims 18–21 are withdrawn from consideration as being drawn to a non-elected invention.

#### ***Claim Rejections – 35 USC § 103***

Claims 1–17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1 213 013 [N] in combination with US 5,935,826 [C] or US 5,185,176 [A].

The claims are directed to a composition comprising an active agent encapsulated in a mixture consisting of a soluble starch derivative which has been derivativized to contain at least a hydrophobic group, and has been degraded by an exoenzyme, wherein the protein is a casein or a soy protein.

EP 1 213 013 discloses the use of casein or soya protein as well as other proteins, to incorporate water insoluble active substances (abstract, page 12, lines 1–18). Also included in the mixture can be starches modified with OSA [0111].

US 5,935,826 disclose the instant starch which has been modified by chemical means (derivativized by octenylsuccinic anhydride to introduce hydrophobicity) and modified by use of  $\beta$ -amylase. Also disclosed is the high level of oxygen resistance (col. 7, l. 23).

US 5,185,176 discloses a water soluble starch which has been degraded by  $\beta$ -amylase and derivativized with OSA which is useful as an emulsifier for oils. Improved shelf stability is obtained with use of this starch derivative.

The substitution of the starch disclosed in US 5,935,826 or US 5,185,176 for the starch in the composition disclosed in EP 1 213 013 would have been obvious because EP '013 suggests the incorporation of modified starches, especially OSA modified starches in a oil-protein composition and such

Art Unit: 1651

modified starches are taught by US 5,935,826 or US 5,185,176 and have known properties of providing excellent oxidation resistance and high loading of oils, and improved shelf life to a composition.

With regard to quantities or ratios of components, these are considered to be routine optimization in the absence of evidence to the contrary.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

### ***Response to Arguments***

Please see CA 2 363 823 which is the English language equivalent of EP 1 213 013, attached to this action. Applicants argue that EP 1 213 013 does not teach the encapsulation of active agent. This is incorrect. See EP 1 213 013 or CA 2 363 823 on page 23, l. 8, where carotenoids (one of the many active agents suggested in the reference) are encapsulated with protein, preferably casein or caseinate (page 20, l. 29) or soybean protein (p. 16, l. 43). In addition to the protein, starch may also be added, for example Na octenyl succinate starch (page 23, ls. 23-29).

Applicants further argue that OSA starch is taught as one of many possible optional additives to the dispersed phase, but that the instant invention uses starch to encapsulate the active agent in the continuous phase. It is unclear what applicants intend by this statement because the composition AS CLAIMED comprises a) active agent, b) a protein, c) modified starch. The composition suggested by the prior art of EP 1 213 013 is a) active agent such as a carotenoid, b) protein such as casein or soy protein, c) modified starch, such as OSA starch. The secondary references provide specific reasons to chose a modified starch such as OSA starch as a component of the composition

Art Unit: 1651

of EP 1 213 013 because of the well known properties of the OSA starch. Thus, the prior art provides specific reasons to chose this specific starch from the list of additional protecting colloids listed in the primary reference. The expectation of some advantage is the strongest rationale for combining references.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

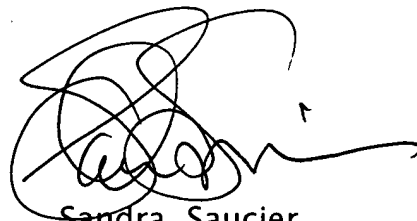
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926. The

Art Unit: 1651

fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Sandra Saucier', with a large, stylized circular flourish above the name.

Sandra Saucier

Primary Examiner

Art Unit 1651

December 29, 2006